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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-16AHI; Docket No. CDC-2016-0041]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project entitled "Community-Based Organization Outcome Monitoring Projects for CBO HIV Prevention Services Clients".

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0041 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information

collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy

of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

"Community-Based Organization Outcome Monitoring Projects for CBO HIV Prevention Services Clients" - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP),

Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Community-Based Organizations (CBOs) play an essential role in reaching persons at high risk of transmitting and acquiring HIV infection. Through Cooperative Agreement #CDC-RFA-PS15-1502 (CBO-HPS), CDC funds 90 CBOs to provide comprehensive HIV prevention services to HIV-positive persons and high-risk HIV-negative persons. However, the CBO-HIV Prevention Services (HPS) awardees are not required to monitor or report on critical outcomes such as whether HIV-positive persons who are linked to HIV medical care were retained in care or prescribed ART, and whether high-risk HIV-negative persons who were referred to Pre-Exposure Prophylaxis (PrEP) initiated its use. Also, CBO-HPS CBOs are not required to collect and report data about clients' perceived barriers to accessing HIV prevention services.

CBO-OMP will fund a subset of CBO-HPS awardees to collect and report data to CDC about the utilization and outcomes of the HIV prevention and support services. This will increase understanding of HIV prevention and support services received by CBO-HPS clients, the outcomes of these services, and successes and challenges related to service provision and utilization.

The respondent universe will comprise clients at 15-18 CBOs funded by CBO-HPS. CBO-OPM is organized in two categories: Category 1- HIV-positive clients and Category 2- high-risk HIV-negative clients.

This information collection will evaluate HIV-prevention services over time through participant interviews, record/ chart review, CBO-HPS staff interviews, and focus groups. Participant interviews will include questions for participants living with HIV-positive and high-risk HIV-negative clients at CBOs funded by CBO-HPS about demographics, HIV-related risk behaviors, HIV prevention and support services received, service outcomes, and experiences with services over time; staff interviews about strategies for and barriers to recruiting and engaging clients in HIV prevention and support services; and focus groups with clients who are receiving HIV prevention services at CBOs.

For Category 1, self-reported client interview data will be collected at baseline, 3, 6, 9 and 15 months. For Category 2, self-reported client level data will be collected at baseline, 3, 6, and 9 months. Participants will complete a 30-minute, staff-facilitated interview at baseline and 20-minute staff-facilitated interviews at each follow-up, to assess the outcomes of HIV-prevention services they receive.

This project will also collect information from CBO-HPS Staff. Two CBO-HPS staff interviews will be conducted for Category 1 and two staff interviews will be conducted for Category 2. All interviews are expected to last 2.5 hours.

This project will also collect information from participant focus groups. Respondents will also complete a short demographic questionnaire. Focus groups will occur twice during the project period and will last approximately 90 minutes.

All electronic data will be password protected and accessible only to project staff and direct supervisors. Data will be stored on network drives which are regularly backed up by staff. Participation in this project is strictly voluntary. The consent process will be implemented according to the local/state policies of the funded agencies. Consent forms are provided. The consent process for CBO-OMP involves the agency staff providing an overview of the project that includes a description of the benefits of as well as the risks and discomforts to participation as well as the protections for the respondent's privacy. Participants must sign the consent form prior to enrolling into the project.

The information collected by each funded agency may include personally identifiable information, such as name and contact information, in order to provide continuity of service, follow-up of referrals, schedule follow-up interviews and other outreach activities. Personally identifiable information will be kept in a locked file cabinet and will be accessible only to appropriate agency staff. Any individually identifiable information collected by funded agencies will not be submitted to CDC.

The category 1 information collection will occur over 33 months and will involve up to 15 CBOs. The population targeted by Category 1 are HIV-positive clients who are receiving CBO-HPS services and have been provided a CBO-HPS referral to HIV medical care. They will be screened, interviewed and CBO staff will collect their medical records related to their HIV-medical care visits, CD4 count and viral loads, and prescription to ART.

The Category 2 information collection will occur over 21 months and involve up to 3 CBOs who will target high-risk HIV-negative clients who are receiving CBO-HPS services. CBOs will screen 225 persons each year. CBO staff will collect their medical records about medical care visits, PrEP prescriptions and information about which CBO-HPS referrals. Participants will

be administered a baseline interview as well as interviews at 3 months, 6 months, and 9 months. Each CBO will also conduct two focus groups over the project period, one in each year of the evaluation.

Each of the CBOs funded to participate in this project will be required to submit data they've collected each month to CDC, including the screener, medical records and CBO-HPS referrals, baseline interview, 3-month follow-up interview, 6-month follow-up interview, 9-month follow-up interview, focus groups, and staff interviews, respectively. There is no cost to respondents other than their time. Total burden hours are 1,125.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Response (Hours)	Total Burden (Hours)
General public	Screener Participant Interview Category 1	175	1	3/60	9
Facility office staff	Medical records abstraction Category 1	120	3	3/60	18
CBO-HPS grantees	CBO-HPS Referrals Category 1	120	3	3/60	18
General public	Baseline Interview Category 1	150	1	40/60	100
General public	3,6,9, and 15 Month Follow-up Interview Category 1	120	4	30/60	240
General public	Screener Focus Group Category 1	150	1	3/60	8

General Public	Focus Group Questionnaire Category 1	90	1	2/60	3
General public	Focus Group Category 1	90	1	1.5	135
CBO-HPS grantees	Staff Interview Category 1	30	1	2.5	75
CBO-OMP CBOs	Data submission Category 1 and 2	18	12	10/60	36
General public	Screener Participant Interview Category 2	225	1	3/60	12
Facility office staff	Medical records abstraction Category 2	168	2	3/60	17
CBO-HPS grantees	CBO-HPS Referrals Category 2	168	2	3/60	17
General public	Baseline Interview Category 2	210	1	40/60	140
General public	3,6, and 9 Month Follow-up Interview Category 2	168	3	30/60	252
General Public	Screener Focus group Category 2	30	1	3/60	2
General Public	Focus Group Questionnaire Category 2	18	1	2/60	1
General public	Focus Group Category 2	18	1	1.5	27
CBO-HPS grantees	Staff Interview Category 2	6	1	2.5	15
Total					1,125

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Leroy A. Richardson
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Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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